



INSPECTION REPORT

MAR 02 2007

1799 cust_id
306076 insp_id
5375 site_id

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799

Certificate: 14-R-0144

Site: 001

CHARLES RIVER LABORATORIES

Inspection

Type: ROUTINE INSPECTION

Date: FEB-20-2007

All regulations and standards are in compliance.

Prepared By:


REBECCA CHAFEL, D V M, USDA, APHIS, Animal Care

Title:

VETERINARY MEDICAL OFFICER

Received By:

(b)(6), (b)(7)(c)

Title:

Date:

FEB-20-2007

Date:

FEB-20-2007



INSPECTION REPORT

MAR 05 2007 1799 cust_id
273385 insp_id
26367 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799
Certificate: 14-R-0144

Site: 018
CHARLES RIVER BRF

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection
Type: ROUTINE INSPECTION
Date: FEB-13-2007

The last routine inspection and exit review were conducted on 12/08/05. This routine inspection and exit review were conducted with management and USDA VMO, Earnest Johnson.

Inventory: no animals present.

NO NON-COMPLIANT ITEM (S) IDENTIFIED THIS INSPECTION.

Prepared By:

Earnest Johnson DVM-VMO
EARNEST JOHNSON, V.M.O., USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector ID: 4048

Date:

FEB-13-2007

FEB 23 2007

Received By: (b)(6), (b)(7)(c)

Date:

FEB-13-2007

Title:



INSPECTION REPORT

JAN 17 2007

1799 cust_id
204673 insp_id
33585 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 020

CONSULTING & STAFFING

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection

Type: ROUTINE INSPECTION

Date: JAN-10-2007

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

Prepared By:

Gloria A. McFadden

GLORIA MCFADDEN, D V M , USDA, APHIS, Animal Care

Title:

VETERINARY MEDICAL SERVICE

Received By:

(b)(6), (b)(7)(c)

Title:

Date:

JAN-10-2007

Date:

JAN-10-2007



INSPECTION REPORT

DEC 20 2006

1799 cust_id

308065 insp_id

10596 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 002

CHARLES RIVER RALEIGH

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection

Type: ROUTINE INSPECTION

Date: DEC-12-2006

All items in compliance.

Prepared By:

F BINKLEY, D V M, USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector ID: 1020

Received By: (b)(6), (b)(7)(c)

Title:

Date:

DEC-12-2006

Date:

DEC-12-2006



JAN 04 2007

1799 cust_id
286272 insp_id
16857 site_id

INSPECTION REPORT

CHARLES RIVER
LABORATORIES INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 016

CHARLES RIVER LABORATORIES
- REDFIELD

Inspection
Type: ROUTINE INSPECTION

Date: DEC-19-2006

251 BALLARDVALE ST
WILMINGTON, MA 01887

2.31 (e)(2) REPEAT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e)(2) - Institutional Animal Care and Use Committee (IACUC). A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

- One protocol [REDACTED] did not adequately provide a rationale for the number of animals to be used in the narrative. The protocol stated that the number of animals will be increased or decreased to meet the objectives of training. The number of animals required should be clearly and scientifically justified to assure that no more animals are used than are necessary for scientific validity. All proposals to conduct an activity involving animals must contain a rationale for the numbers of animals to be used and the rationale must be made available to the inspector at the time of inspection. The facility has changed the protocol proposal form since this protocol was approved and is currently revising this protocol.

To be corrected by: January 20, 2007.

2.33 (b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b)(2) - Each research facility shall establish and maintain programs of adequate veterinary care that include: the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care

- Two bottles of xylazine were past the expiration date (11/06). These bottles were not labeled 'expired' and were not separated from all other medications. These medications were intermingled with other pharmaceuticals that are currently being used for covered species at the facility and are therefore ready for use. The licensee must ensure that all medications used in the facility are within date and labeled properly in accordance with standard veterinary practices and manufacturer's recommendations. If expired medications are used in approved acute terminal procedures or on unregulated species, these medications must be labeled accordingly and segregated from all other medications.

This was corrected at the time of inspection.

Prepared By:

JEFFREY BAKER, V.M.O. , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 4052

Received By:

Sent via email

Title:

Date:

DEC-21-2006

Date:

DEC-22-2006



INSPECTION REPORT

JAN 04 2007

1799 cust_id
286272 insp_id
16857 site_id

This inspection and outbriefing was conducted by the facility staff, Tanya Tims, Veterinary Medical Officer, and Jeff Baker, Veterinary Medical Officer.

Note: The facility still has animals with interdigital lesions, which they are identifying and treating. The facility is comparing three types of flooring to determine how best to house these animals. One type seems to be working better than the other two. This flooring will be in place in three of the rooms by February 2007. This situation will be reevaluated after the animals have spent an adequate amount of time on the new flooring.

Prepared By:

JEFFREY BAKER, V.M.O. , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 4052

Received By:

Sent via email

Title:

Date:

DEC-21-2006

Date:

DEC-22-2006



INSPECTION REPORT

JUL 02 2007

1799 cust_id
293275 insp_id
16728 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 014

CHARLES RIVER LABORATORIES

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection
Type: ROUTINE INSPECTION
Date: JUN-25-2007

2.31 (d X 1 X ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) IACUC: Proposed animal activities must meet the following requirement. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

The principal investigator for animal activity proposal 012-169 has not provide a written narrative description of the methods and sources used to determine that alternatives were not available to the painful/distressful procedure described in the proposal under question 13. The investigator must provide the required information to comply with the Animal Welfare regulations and to ensure that animal pain and distress in minimized.

Correct by August 1, 2007.

3.56 (c)

SANITATION.

Section 3.56(c) Housekeeping: Premises shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart.

The equipment cart in animal room H1 had two dirty clippers, brushes with animal hair, dirty plastic collars and accumulations of animal hair. The equipment cart with the computer, scales and supplies in animal room H2 was dusty/dirty with the dust bin and brush stored on the cart.

Equipment and supplies used on animals need to be kept clean to maintain the health of the animals. Items necessary for performing the study and maintaining the animal room need to be kept clean and stored appropriately. During the inspection the carts, equipment and supplies were cleaned and the dust bin and brush removed from the cart.

Corrected during the inspection.

Prepared By:

Mary Geib

MARY GEIB, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector ID: 1021

Date:

JUN-26-2007

Received By: (b)(6), (b)(7)(c)

Title:

Date:

JUN-26-2007



MAY 29 2007

SDRLICA

1799 cust_id

271516 insp_id

10600 site_id

INSPECTION REPORT

CHARLES RIVER
LABORATORIES INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 005

CHARLES RIVER LABORATORIES
- SPARKS

Inspection
Type: ROUTINE INSPECTION

Date: MAR-22-2007

251 BALLARDVALE ST
WILMINGTON, MA 01887

2.32 (a)

PERSONNEL QUALIFICATIONS.

Sec. 2.32 Personnel qualifications. (a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. (c) Training and instruction of personnel must include guidance in at least the following areas: (1) Humane methods of animal maintenance and experimentation, including: (ii) Proper handling and care for the various species of animals used by the facility;

For three days, animals were being injured when they were moved by employees unfamiliar with techniques used to prevent fingers from being trapped on the downward side of the cage. The facility stated that new employees were doing the moving and they were not properly trained to move the animals. The primate's digits were trapped on the bottom of the cage enclosure when placed on the transport cart. Individuals transporting animals should have been trained prior to moving animals to prevent animal injury. The training of employees occurred after 3 days of animals being transported with the following animals being injured

The facility trained the personnel on moving the animals after three days of injuries. There have no incidents according to the facility since the training.

3.80 (a) (2)

PRIMARY ENCLOSURES.

?3.80 Primary enclosures. Primary enclosures for nonhuman primates must meet the following minimum requirements: (a) General requirements. (2) Primary enclosures must be constructed and maintained so that they: (x) Have floors that are constructed in a manner that protects the nonhuman primates from injuring themselves;

The animal enclosures were placed in a manner that did not protect the animals from injury. A surface was placed on transport carts causing injury to digits in primates. The enclosures should be placed in such a way that does not cause injury to the animals. Solid surfaces should be placed downward to prevent animal injury.

On 11/29/06 #mf 39210 m, a non human primate was being moved in it's crate to another area. During transport, it got its fingers caught between the wiring of the cage and the surface of the transporter (dolly or a flat bed cart). Phalanx 1,2,3 of D4 was amputated.

On 11/30 06 # mf12313m, a non human primate was being moved in it's crate to another area. During transport, it got its

Prepared By:

STEVEN DRLICA, V.M.O. , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 5004

Received By:

(b)(6), (b)(7)(c)

Title:

Date:

MAY-04-2007

Date:

MAY-04-2007



29 2007

SDRLICA

INSPECTION REPORT

1799 cust_id
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10600 site_id

fingers caught between the wiring of the cage and the surface of the transporter (dolly or a flat bed cart). D2 digit on the left hand had to be amputated.

On 11/30/06 #mf 94296 m, a non human primate was being moved in it's crate to another area. During transport, it got its fingers caught between the wiring of the cage and the surface of the transporter (dolly or a flat bed cart). Removed D2.

On 12/01/06 #mf 22218 f, a non human primate was being moved in it's crate to another area. During transport, it got its tail caught between the wiring of the cage and the surface of the transporter (dolly or a flat bed cart). The tail tip was lacerated and had to be treated.

The situation was corrected after 3 days. The cause of these incidents were corrected prior to the USDA inspection, and the facility needs to ensure that all future moves are safe for the animals.

Another incident was reported to the IACUC on the December 2006 report. This animal went through a lit hole in the squeeze portion of the cage. Somehow during the episode, the animal ended up breaking a front leg. This appeared to be a one time "freak" accident and the committee did not take any action on the incident.

There have not been any reported incidents since the animal broke its leg according to the facility.

Comment: Some additional issues with the primary enclosures are under review.

Prepared By:

STEVEN DRLICA, V.M.O. , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 5004

Date:

MAY-04-2007

Received By:

(b)(6), (b)(7)(c)

Title:

Date:

MAY-04-2007



INSPECTION REPORT

1799 cust_id
201669 insp_id
16727 site_id

**CHARLES RIVER LABORATORIES
INC**

Customer ID: 1799

Certificate: 14-R-0144

JAN 17 2007

Site: 013

CHARLES RIVER LABORATORIES

**251 BALLARDVALE ST
WILMINGTON, MA 01887**

Inspection

Type: ROUTINE INSPECTION

Date: JAN-09-2007

3.1 (a)

HOUSING FACILITIES, GENERAL.

3.1 (a) - "Housing facilities for dogs.....must be kept in good repair."

1. There was a broken ceiling mounted light fixture cover identified in 55-B54. Animal housing facilities must be kept in good repair. Facility corrected by replacing the light fixture cover during the inspection.

3.6 (a) (1)

PRIMARY ENCLOSURES.

3.6 (a) (1) - "The primary enclosures must be kept in good repair."

1. A heavy duty wire used to secure the front chain link wall of an enclosure in 55-B102 was noted to be broken and one end of the wire protruded into the enclosure. This situation could result in an injury to the animals. Facility corrected by replacing the heavy duty wire at the time of the inspection.

3.80 (a) (2) (i)

PRIMARY ENCLOSURES.

3.80 (a) (2) (i) - "Primary enclosures must be constructed and maintained so that they: (i) Have no sharp points or edges that could injure the nonhuman primates."

1. There was a feed receptacle mounted on the front of an enclosure in 57-243 that had a broken wire on the inside that was bent and sticking upwards. This situation could result in injury to the animal. Facility immediately corrected by discarding and replacing the feed receptacle.

3.84 (a)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

3.84 (a) - "Cleaning of primary enclosures. Excreta and food waste must be removed from inside each indoor primary enclosure daily.....to prevent an excessive accumulation of feces and food waste."

1. There were several enclosures in 55-303 and 55-304 that were noted to contain an accumulation of fecal matter inside the enclosure compared to the other enclosures in the room. Increased excreta inside primary enclosures can cause odors, animal soiling, and health hazards. Facility corrected during the inspection by removing the excreta from the enclosures.

Prepared By:

Paula Gladue
PAULA GLADUE, V M D , USDA, APHIS, Animal Care

Title:

(b)(6), (b)(7)(c)

Received By:

Title:

Date:

JAN-10-2007

Date:

JAN-10-2007



INSPECTION REPORT

DEC 27 2006

1799 cust_id

117722 insp_id

21528 site_id

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799

Certificate: 14-R-0144

Site: 017

OHIO SITE

Inspection

Type: ROUTINE INSPECTION

Date: DEC-19-2006

No Non compliances identified this inspection.

Inspection and exit interview with Attending Veterinarian, Manager of Regulatory Compliance, and General Manager

Prepared By:

Clara Markin

CLARA MARKIN, D.V.M., USDA, APHIS, Animal Care

Title: (b)(6), (b)(7)(c)

012

Received By:

Title:

Date:

DEC-19-2006

Date:

DEC-19-2006



INSPECTION REPORT

1799 cust_id
293166 insp_id
16728 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 014

CHARLES RIVER LABORATORIES

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection
Type: ROUTINE INSPECTION
Date: DEC-11-2006

2.33 (b)(3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b)(3) Veterinary care: Each research facility shall establish and maintain programs of adequate veterinary care that include daily observation of all animals to assess their health and well-being with direct and frequent communication so timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

Animal activity proposal VMH0004A includes potential side effects (Question 15 on page 11) and states that animals with adverse clinical effects will be immediately addressed by the Study Director and/or veterinary staff. Euthanasia is described as the disposition of animals in pain and/or distress (Question 17 on page 12).

Adverse clinical effects were observed for animal 9707 on day 4 and for animal 9706 on day 11. These animals were not euthanized and there were no requests for a veterinarian to exam the animals. Both of these animals were found dead the following day. This study has been completed. The attending veterinarian must be kept informed about problems of animal health and animals must receive the appropriate care to minimize pain and distress as specified and approved by the IACUC.

Correct for future proposals.

Prepared By:

Mary Geib

MARY GEIB, D.V.M., USDA, APHIS, Animal Care

Title:

(b)(6), (b)(7)(c)

Received By:

Title:

Date:

DEC-12-2006

Date:

DEC-12-2006



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INSPECTION REPORT

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1799 cust_id

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29646 site_id

BY:

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 019

RIVER VALLEY FARMS

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection
Type: ROUTINE INSPECTION
Date: OCT-30-2006

No covered animals at the time of inspection.

No noncompliances identified on this inspection.

End of report.

Prepared By:

DEBRA SIME, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 1072

Received By:

Sent by certified mail.

Title: RECEIPT #7005 1820 0005 0919 9349

Date:

OCT-30-2006

Date:

OCT-30-2006

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Charles River Laboratories
251 Ballardvale ST.
Wilmington, MA 01887



PS Form 3811, July 1999

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) B. Date of Delivery

11-3-06

C.
X (b)(6), (b)(7)(c)D. Is delivery restricted? ☐ Yes ☒ No
If YES, enter delivery address below:

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- | | |
|---|---|
| ☐ Certified Mail | ☐ Express Mail |
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4. Restricted Delivery (Extra Fee) ☐ Yes

7005 1820 0005 0919 9349

Domestic Return Receipt

102595-00-M-0952

14-R-0144

14-B-0013



SEP 11 2006

MGEIB1

1799 cust_id

293118 insp_id

16728 site_id

INSPECTION REPORT

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799

Certificate: 14-R-0144

Site: 014

CHARLES RIVER LABORATORIES

Inspection

Type: ROUTINE INSPECTION

Date: AUG-29-2006

2.31 (d X 1 X ii) REPEAT NCI

2.31 (d X 1 X iv X A)

2.31 (d X 2) REPEAT NCI

2.31 (e X 3) REPEAT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) IACUC: Proposed animal activities must meet the following requirement. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

The principal investigator for animal activity proposal 012-116R still has not provide a written narrative description of the methods and sources used to determine that alternatives were not available to the painful/distressful procedure. The investigator must provide the required information to comply with the Animal Welfare regulations and to ensure that animal pain and distress in minimized.

Section 2.31(d)(1)(iv)(A) IACUC: Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.

The principal investigator for animal activity proposal GTA00034 under section 13B checked yes that pain/distress will be relieved with anesthetics, analgesics or tranquilizers; then stated that the drugs would not be used, but supportive care would be provided by the veterinary staff. The principal investigator did not provide justification for not using anesthetics, analgesics, or tranquilizers. This proposal has been completed. Future proposals need to accurately indicate if pain/distress can be relieved with anesthetics, analgesics or tranquilizers. The principal investigators must provide written scientific justification for not using anesthetics, analgesic or tranquilizers to minimize or prevent animal pain/distress.

Correct by August 31, 2006.

Section 2.31(d)(2) IACUC: Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities.

Prepared By:

Mary Geib
MARY GEIB, D.V.M., USDA APHIS, Animal Care

Title: (b)(6), (b)(7)(c)

1021

Date:

AUG-30-2006

Received By:

Title:

Date:

AUG-30-2006



11 2006

MGEIB1

1799 cust_id

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16728 site_id

INSPECTION REPORT

Since the last inspection the IACUC approved an expedited protocol amendment review process (34A:12.8) which allows the Chair, Veterinarian or their designee to review and approve a time-dependent request. Then the change is reviewed and approved by the full committee as the next meeting. This procedure was documented in the meeting minutes of meetings that occurred since the last inspection. This expedited protocol amendment review process is not compliant with the animal welfare regulations. The IACUC members did not have an opportunity to request additional information or request a full IACUC meeting before the amendment was approved by the IACUC designated reviewer. The committee does not re-review and vote on proposals and amendments after they are approved by the designated reviewer and the animal work started. The IACUC members must have the opportunity to request a full Committee review before the animal activity proposal or amendment is given to the IACUC designated reviewer.

Section 2.31(e)(3) IACUC: A proposal to conduct an activity involving animals must contain a complete description of the proposed use of the animals.

Animal activity proposals FIA00332 and QKF00005 were modified, but are still confusing and inconsistent. Both proposals state that animal pain and distress can not be relieved (Question 1), but both proposals in other sections state that if adverse effects occur then a plan of action will be developed to ensure that no more than momentary pain or distress will occur (FIA00332 page 28 & QKF00005 page 14).

Animal activity proposal GTA00016 was approved since the last inspection and states that animal pain and distress can not be relieved (Question 1). However, the proposal also states that should adverse effects occur then action will be taken to minimize and/or prevent more than momentary pain/distress (page 14).

Future proposals must be clear and consistent so animals will receive pain/distress relief as specified in the proposal.

Prepared By:

Mary Geib

MARY GEIB, D V M , USDA, APHIS, Animal Care

Title: (b)(6), (b)(7)(c)

Received By:

Title:

Date:

AUG-30-2006

Date:

AUG-30-2006



JUL 03 2006

PGLADUE

1799 cust_id

201593 insp_id

10597 site_id

INSPECTION REPORT

**CHARLES RIVER LABORATORIES
INC**

**251 BALLARDVALE ST
WILMINGTON, MA 01887**

Customer ID: 1799

Certificate: 14-R-0144

Site: 003

PHARMSERVICES - BLACKMER

Inspection

Type: ROUTINE INSPECTION

Date: JUN-26-2006

3.1 (f)

HOUSING FACILITIES, GENERAL.

3.1 (f) - "Trash containers in housing facilities.....must be leakproof and must have tightly fitted lids on them at all times."

1. There was an uncovered trash receptacle containing discarded items and used bedding in the procedure room of Bldg I. Trash receptacles should have a tightly fitting lid. Item was corrected by the facility at the time of the inspection.

3.9 (b)

FEEDING.

3.9 (b) - "Food receptacles.....must be located so as to minimize contamination."

1. The primary enclosures housing dogs in I-102A were in the process of being cleaned and the wooden shavings bedding material replaced at the time of the inspection. The room was inspected immediately after the cleaning was completed. The food receptacles in some of the dogs' enclosures contained wood shavings that completely covered the dog chow in the bowl. Food receptacles should be located to minimize contamination of the feed. Facility corrected the item during the inspection.

Animal species inspected - Dogs; Swine; Sheep; Goats

Last inspection - 8/9/05

Prepared By:

Title:

Received By:

Title:

at Care

ID: 1054

Date:

JUN-27-2006

Date:

JUN-27-2006



INSPECTION REPORT

MAY 20 2006 1799 cust_id
271300 insp_id
10600 site_id

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799

Certificate: 14-R-0144

Site: 005

SPARKS, NV - R

Inspection

Type: ROUTINE INSPECTION

Date: MAY-23-2006

No non compliant items identified on this inspection.

This was a partial inspection: Animal facilities and animals.

Prepared By:

Stine Delea DVM

Title:

(b)(6), (b)(7)(c)

Animal Care

Received By:

or ID: 5004

Title:

Date:

MAY-23-2006

Date:

MAY-23-2006



JUN 20 2006

SDR/ICA

1799 cust_id

271316 insp_id

10600 site_id

INSPECTION REPORT

**CHARLES RIVER LABORATORIES
INC**

Customer ID: 1799

Certificate: 14-R-0144

Site: 005

SPARKS, NV - R

**251 BALLARDVALE ST
WILMINGTON, MA 01887**

Inspection

Type: ROUTINE INSPECTION

Date: JUN-02-2006

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC) (c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

For the minor deficiencies, no reasonable and specific plans of action are documented in the semi annual report of February 22, 2006. No correction dates are present in the report (However, other documents do have work orders and corrected dates). And, no mention for the reason for the departures is mentioned in the report. Creating a specific report for the semi annual review with the elements outlined in 2.31c3 will resolve this issue. This is important so the proper officials are notified so the corrections can be made.

To be corrected by with the next semi annual review in August.

Exit Interview with the AO(Administrative Officer), Attending Vet, the IACUC Chairman, and others.

Prepared By:

Steven Drlica

STEVEN DRLICA, V.M.O., USDA, APHIS, Animal Care

Title:

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) ID: 5004

Received By:

(b)(6), (b)(7)(c)

Title:

Date:

JUN-02-2006

Date:

JUN-02-2006



2006

DSIME

1799 cust_id

244485 insp_id

29646 site_id

INSPECTION REPORT

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799

Certificate: 14-R-0144

Site: 019

RIVER VALLEY FARMS

Inspection

Type: ROUTINE INSPECTION

Date: JUN-08-2006

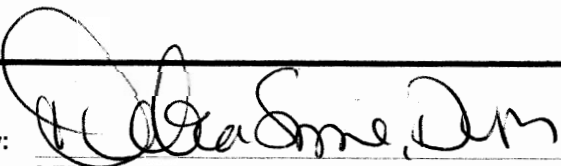
This is the amended inspection report to reflect the correct last inspection date.

Last inspection: 22 June 2005.

No noncompliances identified on this inspection.

End of report.

Prepared By:


DEBRA SIME, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 1072

Received By:

Sent by certified mail.

Title: RECEIPT #7005 0390 0005 1002 1773

Date:

JUN-30-2006

Date:

JUN-30-2006

1299

14-K-
0144

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Charles River Labs
251 Ballouville ST
Wilmington, MA 01887

2. Article Number
(Transfer from service label)

7005 0390 0005 1002 1773

COMPLETE THIS SECTION ON DELIVERY

A. Signature

(b)(6), (b)(7)(c)

- ☐ Agent
☐ Addressee

(b)(6), (b)(7)(c)

C. Date of Delivery

7/5/06

in 1? ☐ Yes

If YES, enter delivery address below: ☐ No

3. Service Type

- ☐ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes



JUN 16 2006

DSIME

INSPECTION REPORT

1799 cust_id

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29646 site_id

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799

Certificate: 14-R-0144

Site: 019

RIVER VALLEY FARMS

Inspection

Type: ROUTINE INSPECTION

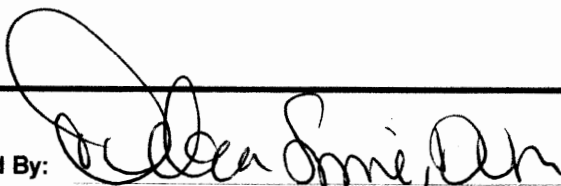
Date: JUN-08-2006

Last inspection: 22 June 2006 ¹⁵ ^{DS}

No noncompliances identified on this inspection.

End of report.

Prepared By:


DEBRA SIME, D V M , USDA, APHIS, Animal Care

Title:

(b)(7)(c)

72

Received By:

Title:

Date:

JUN-08-2006

Date:

JUN-08-2006



INSPECTION REPORT

JUN 02 2006

1799 cust_id
245261 insp_id
5375 site_id

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799
Certificate: 14-R-0144

Site: 001

CHARLES RIVER LABORATORIES

Inspection
Type: ROUTINE INSPECTION
Date: MAY-24-2006

2.31 (d) (1) (ii)

2.31 (e) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(d)(1) Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

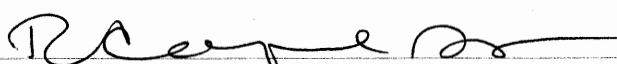
(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources.

****Protocol (b)(4) The principal investigator did not consider alternatives to the painful procedures described in this protocol. Animals in this protocol may undergo tissue harvest under anesthesia, prior to euthanasia. Alternatives to the procedures involved in tissue harvesting must be considered. IACUC must address this issue. Correct by 7/7/06.

2.31(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

(4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.

****Protocol (b)(4) The hamster anesthesia dosing described in this protocol differs from the referenced hamster anesthesia dosing described in SOP-761-2. Protocol (b)(4) states that hamsters will receive 200 mg/kg of ketamine whereas the referenced SOP-761-2 states that hamsters will receive 100 mg/kg of ketamine. This difference in anesthesia dosing needs to be addressed in order to assure appropriate anesthesia. IACUC must address this issue. Correct by 7/7/06.

Prepared By: 
REBECCA CHAFEL, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector ID: 1071

Received By: (b)(6), (b)(7)(c)

Title:

Date:
MAY-24-2006

Date:
MAY-24-2006



INSPECTION REPORT

APR 17 2006

1799 cust_id
293014 insp_id
16728 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 014

CHARLES RIVER LABORATORIES

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection
Type: ROUTINE INSPECTION
Date: APR-12-2006

2.31 (c) (3)

2.31 (d) (1)

2.31 (d) (2)

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(c)(3) IACUC: The IACUC report must contain a plan and schedule with dates for correcting each deficiency.

The IACUC report for March of 2006 did not include a plan and correction date for every deficiency noted. The plan for room maintenance issues referred to a schedule that did not include any time frame or date for correcting the deficiencies. Also the schedule was not included in the IACUC report. The IACUC report to the Institutional Official must include a plan and correction date for every deficiency noted to comply with the Animal Welfare regulations and to keep the Institutional Official informed. Correct by May 15, 2006.

Section 2.31(d)(1) IACUC: Proposed animal activities must meet the following requirements.

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

(iv)(A) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.

The principal investigator for animal activity proposal 012-116R did not provide a scientific justification for not relieving animal pain or distress and did not provide a written narrative description of the methods and sources used to determine that alternatives were not available to the painful/distressful procedure. The investigator must provide the required information to comply with the Animal Welfare regulations and to ensure that animal pain and distress is minimized. Correct by May 15, 2006.

Section 2.31(d)(2) IACUC: Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities.

Prepared By:

Mary Gail D.V.M.

MARY GAIL D.V.M. USDA APHIS Animal Care

Title: (b)(7)(c), (b)(6)

Date:

APR-12-2006

Received By:

Title:

Date:

APR-12-2006



INSPECTION REPORT

APR 17 2006

Amendment 1 for animal activity proposal FIA00332 was approved by the designated IACUC reviewer on April 3, 2006; the same day that it was sent to the IACUC members. The facility's IACUC gives members 48 hours to request a full Committee review. The IACUC members did not have an opportunity to request additional information or request a full IACUC meeting before the amendment was approved by the IACUC designated reviewer. IACUC members must have the opportunity to request a full Committee review before the animal activity proposal or amendment is given to the IACUC designated reviewer. Correct from this day forward.

Section 2.31(e)(3) IACUC: A proposal to conduct an activity involving animals must contain a complete description of the proposed use of the animals.

Animal activity proposals FIA00332 and QKF00005 are confusing and inconsistent. Both proposals state that animal pain and distress can not be relieved, but both proposals in other sections state that if adverse effects occur then a plan of action will be developed to ensure that no more than momentary pain or distress will occur. These proposals must be clear and consistent so animals will receive pain/distress relief as specified in the proposal. Correct by May 15, 2006.

2.36 (b) (7)

ANNUAL REPORT.

Section 2.36(b)(7) Annual report: State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report.

At least 6 rabbits had significant skin lesions from the injection of an irritation drug on animal activity proposal DUK00008 conducted during December of 2004 and January of 2005. The following size skin lesions in the animals were noted in the study data: 2 cm diameter (#342); 4 cm by 3.5 cm (#351); 4 cm by 2.5 cm (352); 2 cm by 1.5 cm (#353); 4 cm by 3 cm and 2 cm in diameter (#354); and 9 cm by 4 cm and 4 cm by 2 cm (#355). The inflammatory reaction necessary to produce the skin lesions would be expected to cause the animals pain/distress. No treatment was given. These animals were not reported in Category E. Also the annual report lists 33 rabbits in Category E, but there are explanations for 34 rabbits in Category E. Annual reports must accurately report the research facility's animal usage to comply with the Animal Welfare regulations. The 2005 Annual Report for this research facility must be amended and submitted to the Eastern Regional Director:

Dr. Elizabeth Goldentyer
USDA, APHIS, AC
Eastern Regional Office
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Correct by June 15, 2006.

Prepared By:

Mary Gail

Title:

(b)(6), (b)(7)(c)

Received By:

Title:

Date:

APR-12-2006

Date:

APR-12-2006



MAR 28 2006

PGLADUE

1799 cust_id

201549 insp_id

16727 site_id

INSPECTION REPORT

**CHARLES RIVER LABORATORIES
INC**

Customer ID: 1799

Certificate: 14-R-0144

Site: 013

CHARLES RIVER LABORATORIES

Inspection

Type: ROUTINE INSPECTION

Date: MAR-21-2006

**251 BALLARDVALE ST
WILMINGTON, MA 01887**

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (5) - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

1. The medical record for Rabbit #30 used under Protocol (b)(4) was reviewed. The Rabbit weighed 4.1 kg at the start of the study on 12/1/05. The animal's weight was recorded weekly. The Rabbit's weight gradually decreased to 3.0 kg by study day 48. There was no documentation in the medical record that the weight loss had been evaluated. However, according to personnel, the weight loss had been discussed by staff and changes implemented but this information had not been documented in the medical record. Corrected at the time of the inspection by the Attending Veterinarian who evaluated the Rabbit and reviewed documentation procedures with staff during the inspection.

3.6 (a) (1) (ii)

PRIMARY ENCLOSURES.

3.6 (a) (2) (ii) - "Primary enclosures must be constructed and maintained so that they: (ii) Protect the dogs and cats from injury."

1. Some of the Dogs housed in 57-B48 were observed while being provided exercise at the time of the inspection. The dogs were allowed to move freely and there was not any facility personnel present in the room. The room and primary enclosures were being cleaned and there was a mop and bucket containing a cleaning solution on the floor that was accessible to the dogs. This situation could be hazardous to the dogs from ingestion of the cleaning solution or from other methods of contact. The facility immediately corrected the situation at the time of the inspection.

3.11 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

3.11 (c) - "Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury."

1. One of the ceiling mounted light fixture covers in 55-B123 directly above an enclosure housing Dogs was not secured at one corner and was hanging down. Facility corrected at the time of the inspection.

Prepared By:

Paula Gladue
PAULA GLADUE, VMD / USDA, APHIS, Animal Care

Title: (b)(6), (b)(7)(c)

054

Date:

MAR-23-2006

Received By:

Title:

Date:

MAR-23-2006



MAR 28 2006

PGLADUE

1799 cust_id

201549 insp_id

16727 site_id

INSPECTION REPORT

3.53 (a) (1)

PRIMARY ENCLOSURES.

3.53 (a) (1) - "Primary enclosures shall be structurally sound and maintained in good repair to protect the rabbits from injury."

1. A wire spring that is used to attach a J feeder to an enclosure was noted to be inside a Rabbit enclosure in 57-540. One end of the spring was caught on the flooring and the other end was sticking up and could be a hazard to the Rabbit. The spring was removed by facility personnel at the time of the inspection.

3.80 (a) (2) (ii)

PRIMARY ENCLOSURES.

3.80 (a) (2) (ii) - "Primary enclosures must be constructed and maintained so that they: (ii) Protect the nonhuman primates from injury."

1. One of the NHP's in 57-237 had pulled the coiled rubber water hose into its enclosure through the top of its cage so that it formed a loop. This situation could pose a hazard to the animal. Personnel corrected the situation at the time of the inspection.

3.81 (c) (2)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

3.81 (c) (2) - "Special considerations. Certain nonhuman primates must be provided special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Nonhuman primates requiring special attention are the following: (2) Those that show signs of being in psychological distress through behavior or appearance."

1. NHP #0403063 in 57-232 was noted by the inspector to be exhibiting the stereotypic behavior of saluting at the time of the inspection. The condition had not been previously noted by facility personnel. The NHP was evaluated and a treatment plan developed for the stereotypic behavior during the inspection.

3.84 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

3.84 (c) - " Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair."

1. The inside of the two refrigerators in 55-308 were noted to be dirty and had a red colored liquid on the shelves. Some of the liquid had spilled on the floor in front of one of the refrigerators.
2. The sliding door tracks of the wall mounted cabinets in 55-308 were dirty and had particulate material present.
3. One of the ceiling mounted air vents above a surgery table in 57-344 was noted to be rusty.

Premises must be kept clean in order to facilitate proper husbandry practices. The presence of rust on objects can interfere with the sanitization of surfaces. Correct 1 and 2 by March 24, 2006. Correct 3 by March 31, 2006.

NOTE - This was a full facility inspection conducted from 3/21/06 through 3/23/06.

Prepared By:

Paula Gladue
PAULA GLADUE, VMD, USDA, APHIS, Animal Care

Title: (b)(6), (b)(7)(c)

Date:

MAR-23-2006

Received By:

Title:

Date:

MAR-23-2006



MAR 15 2006

GMCFADDEN

INSPECTION REPORT

1799 cust_id
204532 insp_id
33585 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 020

CONSULTING & STAFFING

251 BALLARDVALE ST
WILMINGTON, MA 01887

Inspection
Type: ROUTINE INSPECTION
Date: MAR-06-2006

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.
No animals are present for this inspection.

Prepared By:

Gloria A. McFadden

GLORIA MCFADDEN, D V M , USDA, APHIS, Animal Care

Title:

VETERINARY MEDICAL OFFICER Inspector ID: 1048

Received By:

(b)(6), (b)(7)(c)

Title:

Date:

MAR-06-2006

Date:

MAR-06-2006



INSPECTION REPORT

MAR 20 2006

1799 cust_id

117604 insp_id

21528 site_id

CHARLES RIVER LABORATORIES
INC

251 BALLARDVALE ST
WILMINGTON, MA 01887

Customer ID: 1799

Certificate: 14-R-0144

Site: 017

OHIO SITE

Inspection

Type: ROUTINE INSPECTION

Date: MAR-14-2006

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) IACUC - IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing;

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available;

Guinea pig protocols , LMT 49 , NPB 22, are skin sensitization tests. The PI has not considered approved potential alternative methods , (eg LLNA) as an alternative to these test that may cause more than slight or momentary pain or distress to animals . There are no written justifications for not using these potential alternative methods in the protocol.

In order to assure the welfare of the animals , the IACUC must ensure that PI's consider alternatives to procedures that may cause more than momentary or slight pain or distress to animals and document that appropriate alternatives were not available.

CORRECT BY 04-30-06

SITES : Main :276 Canines, 8 Rabbits

Annex : 92 Canines, 70 Rabbits, 87 Guinea Pigs

Inspection was conducted with Senior Director of Compliance , Attending Veterinarian, & Jodie Kulpa Eddy DVM

Prepared By:

Clara Markin

CLARA MARKIN, D V M , USDA, APHIS, Animal Care

Title:

(b)(6), (b)(7)(c)

Received By:

[Signature]

Title:

Date:

MAR-14-2006

Date:

MAR-14-2006



INSPECTION REPORT

MAR 20 2006

1799 cust_id

163875 insp_id

36966 site_id

CHARLES RIVER LABORATORIES
INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 021

KINGSTON SITE

Inspection

Type: ROUTINE INSPECTION

Date: MAR-13-2006

251 BALLARDVALE ST
WILMINGTON, MA 01887

No non-compliant items identified this inspection.

Prepared By: *Nancy H. [Signature]*

Title: (b)(6), (b)(7)(c)

Received By:

Title:

Date:

MAR-13-2006

Date:

MAR-13-2006



INSPECTION REPORT JAN 20 2006

1799 cust_id

171865 insp_id

10596 site_id

**CHARLES RIVER LABORATORIES
INC**

Customer ID: 1799

Certificate: 14-R-0144

Site: 002

CHARLES RIVER RALEIGH

**251 BALLARDVALE ST
WILMINGTON, MA 01887**

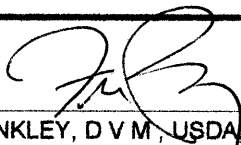
Inspection

Type: ROUTINE INSPECTION

Date: JAN-10-2006

All items in compliance.

Prepared By:


F BINKLEY, D V M, USDA, APHIS, Animal Care

Title:

(b)(6), (b)(7)(c)

: 1020

Received By:

Title:

Date:

JAN-10-2006

Date:

JAN-10-2006